Supplement to
INFORMATION LETTER
NATIONAL CANNERS ASSOCIATION

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FDA REGULATION UNDER FOOD ADDITIVE LAW

(from Federal Register of May 19)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES

Substances Generally Recognized as Safe; Spices, Seasonings, Essential Oils, Natural Extractives

The Commissioner of Food and Drugs, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 701(a), 72 Stat. 1785, 52 Stat. 1055; 21 U.S.C. 348, 371(a)), and pursuant to the authority delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), proposes to amend the food additive regulations by exempting certain food additives from the requirement of tolerances by adding to the list of substances generally recognized as safe (21 CFR 121.101) the following items:

Subpart B—Exemption of Certain Food Additives From the Requirement of Tolerances

§ 121.101 Substances that are generally recognized as safe.

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(e) * * *

(1) Spices and Other Natural Seasonings and Flavorings (Leaves, Roots, Barks, Berries, etc.)

Common name	*Botanical name of plant source*
* * *	* * *
Alfalfa herb and seed	Medicago sativa L.
Ambrette seed	Hibiscus moschatus Moench.
Angelica	Angelica archangelica L. or other spp. of Angelica.
Angelica root	Do.
Angelica seed	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Balm (lemon balm)	Melissa officinalis L.
Chamomile (cammomile), English or Roman.	Anthemis nobilis L.
Chamomile (camomile), German or Hungarian.	Matricaria chamomilla L.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Clover	Trifolium spp.
Elder flowers	Sambucus canadensis L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Hoarhound	Marrubium vulgare L.
Hyssop	Hyssopus officinalis L.
Linden flowers	Tilia spp.
Sage, Greek	Salvia triloba L.
Thyme, wild or creeping	Thymus serpyllum L.

(2) Essential Oils, Oleoresins (Solvent-Free), and Natural Extractives (Including Distillates)

Common name	*Botanical name of plant source*
* * *	* * *
Alfalfa	Medicago sativa L.
Ambrette (seed)	Hibiscus moschatus Moench.
Balm (lemon balm)	Melissa officinalis L.
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Cacao	Theobroma cacao L.
Carrot	Daucus carota L.

(3) Essential Oils, Oleoresins (Solvent-Free), and Natural Extractives (Including Distillates)—Continued

Common name	*Botanical name of plant source*
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chicory	Cichorium intybus L.
Clover	Trifolium spp.
Corn silk	Zea mays L.
Curacao orange peel (orange, bitter, peel).	Citrus aurantium L.
Dandelion	Taraxacum officinale Weber and T. laevigatum DC.
Dandelion root	Do.
Dog grass (quackgrass, triticum)	Agropyron repens (L.) Beauv.
Elder flowers	Sambucus canadensis L. and S. nigra L.
Estragon (tarragon)	Artemisia dracunculus L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Glycyrrhizin, ammoniated	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Hickory bark	Carya spp.
Horsemint	Monarda punctata L.
Hyssop	Hyssopus officinalis L.
Immortelle	Helichrysum augustifolium DC.
Laurel berries	Laurus nobilis L.
Lemon balm (see balm).	
Lemon peel	Citrus limon (L.) Burm. f.
Linden flowers	Tilia spp.
Lupulin	Humulus lupulus L.
Malt (extract)	Hordeum vulgare L., or other grains.
Melissa (see balm).	
Menthol	Mentha spp.
Menthyl acetate	Mentha spp.
Molasses (extract)	Saccharum officinarum L.
Orange, sweet, flowers	Citrus sinensis (L.) Osbeck.
Orange, sweet, peel	Do.
Rose buds	Rosa spp.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose leaves	Do.
Sage, Greek	Salvia triloba L.
Savory, summer	Satureia hortensis L.
Savory, winter	Satureia montana L.
Sloe berries (blackthorn berries)	Prunus spinosa L.
Tamarind	Tamarindus indica L.
Tannic acid	Nutgalls of Quercus infectoria Oliver and related spp. of Quercus. Also in many other plants.
Thyme, wild or creeping	Thymus serpyllum L.
Triticum (see dog grass).	
Violet flowers	Viola odorata L.
Violet leaves	Do.
Zoological name of animal source	
Ambergris	Physeter macrocephalus L.
Castoreum	Castor fiber L. and C. canadensis Kuhl.

(3) Natural Substances used in Conjunction With Spices and Other Natural Seasonings and Flavorings

Common name	*Botanical name of plant source*
Algae, brown (kelp)	Laminaria spp. and Nereocystis spp.
Algae, red	Porphyra spp. and Rhodymenia palmata (L.) Grev.
Dulse	Rhodymenia palmata (L.)

(4) Natural Extractives (Solvent-Free) Used in Conjunction With Spices, Seasonings, and Flavorings

Common name	*Botanical name of plant source*
Algae, brown	Laminaria spp. and Nereocystis spp.
Algae, red	Porphyra spp. and Rhodymenia palmata (L.) Grev.
Apricot kernel (persic oil)	Prunus armeniaca L.
Dulse	Rhodymenia palmata (L.) Grev.
Kelp (see algae, brown).	
Peach kernel (persic oil)	Prunus persica Sieb. et Zucc.
Peanut stearine	Arachis hypogaea L.
Persic oil (see apricot kernel and peach kernel).	
Quince seed	Cydonia oblonga Miller.

Any interested person may, within 30 days from the date of publication of this notice in the Federal Register, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written comments on the proposal or any portion thereof. Such comments should be filed in triplicate.

Dated: May 12, 1960.

[SEAL]

John L. Harvey,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 60-4530; Filed, May 18, 1960; 8:47 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

EXTENSION OF EFFECTIVE DATE FOR CERTAIN SPECIFIED FOOD ADDITIVES

The Commissioner of Food and Drugs, pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Pub. Law 85-929; 72 Stat. 1788; 21 U.S.C. note under sec. 342) and delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), hereby authorizes the use in foods of certain additives for which tolerances have not yet been established or petitions therefor denied. Therefore, the food additive regulations (25 F.R. 2837, 3525) are amended in the following respects:

1. Section 121.86 is amended by adding thereto the following items:

§ 121.86 Extension of effective date of statute for certain specified food additives as direct additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in food, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued establishing or denying tolerances or exemptions from the requirement of tolerances, in accordance with section 409 of the act; whichever occurs first:

Product	Limits	Specified uses or restrictions
• • •	• • •	• • •
3,5-Diiodosalicylic acid		300 parts per million in feed-grade salt for animal use.
Mannitol		If an amount of the food that may reasonably be consumed as an average serving contains 2.5 grams or more of mannitol, the label shall bear a statement of the number of grams of mannitol in an average serving of the food. The average serving shall be expressed in terms of a convenient unit or units of such food or a convenient unit of measure that can be readily understood and utilized by purchasers of such food. The label shall also bear a statement that the consumption of more than 7.5 grams of mannitol at one time or more than 20 grams of mannitol per day may have laxative effects.
Methyl formate		In raisins and currants as a residue from use as a fumigant, applied at a rate of 0.77 milliliter per pound of fruit.
Sorbitol		If an amount of the food that may reasonably be consumed as an average serving contains 5 grams or more of sorbitol, the label shall bear a statement of the number of grams of sorbitol in an average serving of the food. The average serving shall be expressed in terms of a convenient unit or units of such food or a convenient unit of measure that can be readily understood and utilized by purchasers of such food. The label shall also bear a statement that the consumption of more than 15 grams of sorbitol at one time or more than 40 grams of sorbitol per day may have laxative effects.
Starch, oxidized, prepared by treating starch water suspension with sodium hypochlorite and hydrogen peroxide.		As an ingredient and stabilizer in prepared foods.

2. Section 121.87 (25 F.R. 1727, 1772, 2203, 2395, 3526) is amended as follows:

a. The introduction to the section is amended to read:

§ 121.87 Extension of effective date of statute for certain specified food additives as indirect additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in connection with the production, packaging, and storage of food products, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued in accordance with section 409 of the act, whichever occurs first. The extensions are granted under the condition that a minimum quantity of the additive will be incorporated in the food, consistent with good manufacturing practice. While preliminary data show that many of the substances included in the list may not migrate to foods, these are being included pending the completion of additional scientific work involving them.

b. Section 121.87 is further amended by adding thereto the following items:

(a) *General list.*

Product	Limits	Specified uses or restrictions
Damar resin (natural East Indian resin)		As a component of films for food packaging.
Dibutyl phthalate		Do.
Dimerized rosin (made from rosin (wood, gum, or tall oil rosin or blends of these), using sulfuric acid as a catalyst).		Do.
Dimethylcyclohexyl phthalate		Do.
Hydrogenated castor oil phthalate		Do.
Itaconic acid, polymerized		Do.
Maleic anhydride rosin ester		Do.
Nylon resin (polyhexamethyleneadipamide).		In food-handling equipment other than for milk.
Nylon resin (polyhexamethylenesebacamide).		Do.
Nylon resin (copolymer of hexamethyleneadipamide and hexamethylenesebacamide).		Do.
Palmityl stearate		As a lubricant in polystyrene for food packaging.
Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).		Not to exceed 1.48 percent in film wraps for fruits and vegetables.
Sodium dodecylbenzene sulfonate		As a component of films for food packaging.
Sodium lauryl sulfate		As a component of food-packaging material.
Sperm oil, hydrogenated		As a lubricant in polystyrene for food packaging.
Toluene-sulfonamide formaldehyde resin		As a component of films for food packaging.
Triethylene glycol		Do.

3. Part 121 is amended by adding to Subpart A the following new section:

§ 121.88 Extension of effective date of statute for uses of certain sources of radiation in food processing.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for the granting of exemptions from tolerances, the following sources of radiation may be used in connection with the inspection and packaging of foods and control of food processes, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued in accordance with section 409 of the act, whichever occurs first. The extensions are granted under the condition that the exposure of foods to radiation of the specified energies causes neither radioactivity nor any deleterious changes in foods.

Product	Limits	Specified uses or restrictions
Sealed sources of radiation from radioactive isotopes (strontium 90, cesium 137).	....	At energy levels not exceeding 2.2 million electron volts for inspection of foods, food packages, and control of food processes.
X-radiation.....	.....	Energy level of 300-kilovolt peak for inspection of foods, food packages, and control of food processes.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since extensions of time, under certain conditions, for the effective date of the food additives amendment to the Federal Food, Drug, and Cosmetic Act were contemplated by the statute as a relief of restrictions on the food-processing industry.

Effective date. This order shall become effective on the date of signature.

(Sec. 701, 52 Stat. 1055; 21 U.S.C. 371. Interprets or applies 72 Stat. 1786; 21 U.S.C., note under sec. 342)

Dated: May 16, 1960.

[SEAL] JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 60-4604; Filed, May 20, 1960; 8:47 a.m.]